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IN THE

Supreme Court of the United States

OCTOBER TERM, 1944

No. [redacted] 316

RALADAM COMPANY, as Claimant of 62 Packages, more or less, of Marmola Prescription Tablets,
Petitioner,

vs.

UNITED STATES OF AMERICA,
Respondent.

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES CIRCUIT COURT OF APPEALS FOR THE SEVENTH CIRCUIT AND BRIEF IN SUPPORT THEREOF

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No.

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UNITED STATES OF AMERICA,
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PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES CIRCUIT COURT OF APPEALS FOR THE SEVENTH CIRCUIT

To the Honorable Harlan F. Stone, Chief Justice of the United States, and the Associate Justices of the Supreme Court of the United States:

Your petitioner respectfully shows:

STATEMENT OF THE MATTER INVOLVED

These proceedings were commenced by the Government in the United States District Court for the Western District of Wisconsin, on April 11, 1939 (R. 1), for the condemnation of 62 packages, more or less, of a drug product called Marmola on the charge that it is misbranded (R.

5-7) under Sec. 502(j) of the Federal Food, Drug and Cosmetic Act of 1938 [52 Stat. 1040, c. 675; 21 U.S.C., Sec. 301 et seq.]*, an official pamphlet copy of which is hereto attached as an appendix for the Court's convenience. Sec. 502(j) of the Act [21 U.S.C., Sec. 352(j)] provides as follows:

> "Sec. 502. A drug or device shall be deemed to be misbranded—
>
> "(j) If it is dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof."

The Raladam Company, as the longtime owner and distributor of Marmola (R. 18), intervened as claimant (R. 3-5), and, issue having been joined (R. 15), the case was tried without a jury (R. 20), upon the express stipulation that: "The only ingredient of Marmola Prescription Tablets that is involved in this action is the ½ grain of desiccated thyroid contained in each tablet" (R. 19).

The Marmola labeling recommends it *solely* as a treatment for *adults* with obesity *caused by hypothyroidism* but who are otherwise normal and healthy. Persons with any other disease or abnormal condition are warned not to take it (R. 8). The daily dosage in which Marmola is recommended is 4 tablets a day, each of which contains ½ grain of desiccated thyroid, as aforesaid, making a

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*The Government also counted on Secs. 502(a) and 201(n) of the Act [21 U.S.C., Secs. 352(a) and 321(n)], the effective date of which was expressly postponed by Sec. 902(a) thereof [21 U.S.C., Sec. 392(a)] until "twelve months after the date of its enactment," *viz.*, until June 25, 1939, and, therefore, until after the date of the commencement of these proceedings. The theory advanced by the Government for thus seeking to prematurely invoke Secs. 502(a) and 201(n) was that they were needed to aid in the enforcement of Sec. 502(j). However, even if there were any merit in this contention, the fundamental question in the case, *viz.*, whether Marmola is misbranded under Sec. 502(j), is left unchanged for, unless there is a violation of Sec. 502(j), no aid in its enforcement is needed.

total recommended daily dosage of 2 grains of desiccated thyroid a day; and the Marmola labeling further recommends that it be taken for no longer than "sixty to ninety days—if needed that long" (R. 8-9).

The record in this case discloses that the Marmola labeling, in recommending an average dosage of 2 grains of desiccated thyroid for adults with obesity caused by hypothyroidism, but who are otherwise normal and healthy, is in accord with approved medical practice. The medical witnesses who testified for the Government were in agreement that desiccated thyroid is a "specific" for hypothyroidism (R. 86, 88-9, 188-9, 281, 535-6, 586, 613, 630-1, 853, 860-1, 865). According to Dr. Carlson, who is the official consultant of the Food and Drug Administration on such matters (R. 897): "It is *indispensable* at the present time in therapy of hypothyroidism" (R. 902).

Furthermore, virtually all of the medical witnesses who testified for the Government recognized hypothyroidism as being either a cause or contributing factor in the production of obesity (R. 24, 42, 112-13, 186-87, 205, 242, 278-80, 428, 432, 536, 615, 865). Dr. Short, one of the most prominent of the Government's medical witnesses, and a teacher (R. 33) and specialist in this field (R. 35), said: "I don't think anybody would deny" that hypothyroidism is a predisposing or contributing factor in the production of obesity (R. 113). Likewise, Dr. Severinghaus, another leading Government witness, said: "Certainly," when asked whether he recognized hypothyroidism as a cause of obesity (R. 865).

As a result of the foregoing, desiccated thyroid is "widely used" (R. 88) by the medical profession in the treatment of obesity caused or contributed to by hypothyroidism (R. 54, 58, 80, 84-5, 86, 88, 109, 113, 172, 186, 189, 191, 383, 384, 399, 418-9, 420, 426-7, 429, 500, 614-5, 637, 641-2, 643, 682, 683, 856-7, 858, 866-7) and, as has been pointed out hereinabove, this is the very condi-

tion and, in fact, "only" condition that Marmola is recommended for in its labeling, as aforesaid (R. 8).* In addition, the "generally established" (R. 115) average dosage in which desiccated thyroid is prescribed for this condition by the Medical profession *is the same* as the dosage recommended in the Marmola labeling, *viz.*, 2 grains per day (R. 55, 87, 115, 248, 544, 608, 639, 647, 686, 710-11, 892).** Finally, such a dosage is relatively small compared to that which had been prescribed by many of the doctors who testified for the Government (R. 89, 131, 138, 140, 149-50, 194, 393-4, 487, 610, 686-7, 892-3), two of the most prominent of whom had prescribed it in doses up to 50 grains (R. 609, 618, 711, 714) presumably without fear of doing their patients any harm.

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*Furthermore, it should be noted, in this connection, that although Dr. Severinghaus was apparently willing to deny the propriety of using desiccated thyroid in the treatment of obesity, *generally*, when testifying against a patent medicine (R. 866-7), his recent book on "Endocrine Therapy In General Practice," which he gave as one of his qualifications for testifying as an expert in this field (R. 779), contains the following pertinent statement (R. 866):

> "In some patients obesity is lost slowly *except on the use of thyroid* without diet, even though they have a normal basal metabolism and no other evidence of hypothyroidism. For such persons *the use of thyroid* is helpful and constitutes a sort of passive exercise." (Italics ours)

**Of course it is true that the tolerance of all persons for desiccated thyroid is not the same, as is pointed out in the Marmola labeling (R. 9). However, it is approved medical practice to start out with an average dose, and *cut it in half* if it proves to be too high, as disclosed by the appearance of unpleasant and readily recognizable symptoms of overdosage (R. 89-90, 152, 158, 173, 192, 430, 590, 642-3, 892). The Marmola labeling follows this practice by instructing users that: "If any unpleasant effects are experienced stop taking Marmola until they disappear, then resume taking one-half of the former dosage or consult a physician" (R. 9). Moreover, it should be noted that the symptoms which disclose a person's intolerance for a given dosage of desiccated thyroid are mild and purely transitory (R. 89-91, 101, 104, 111, 157-8, 159, 160, 590, 806-7). They appear before any real harm has been done (R. 118), and disappear promptly when the medication is discontinued or the dosage lowered (R. 24, 90-1, 97, 101, 105, 111, 159, 161, 200-1, 202-3, 590, 612, 862-3). In fact, this is the theory upon which specialists in this field, like Dr. Short, are practicing medicine (R. 91).

To summarize the material parts of the record herein, it has been established by the Government's proof alone that the Marmola dosage and directions for use are in accord with what the medical profession itself prescribes. This is so, because the *sole* condition for which Marmola is recommended in its labeling is the very condition for which it is "widely used" by the medical profession, as being the "specific" and "indispensable" treatment for hypothyroidism and obesity so caused or contributed to. Furthermore, the dosage of desiccated thyroid recommended in the Marmola labeling is not only the "generally established" *average* dosage prescribed in such treatment by specialists in this field, but well within the maximum dosage they have prescribed presumably without fear of endangering the health of their patients.

In view of the foregoing, it seems clear that there is no basis for the decision of the Circuit Court of Appeals for the Seventh Circuit herein that Marmola is "dangerous to health" and misbranded within the meaning of a provision of the statute—like Sec. 502(j)—which speaks in terms of *labeling* and makes purely *labeling* requirements. In other words, the fact that Marmola can be taken *according to* the directions and instructions in its labeling without danger to health (as defined by recognized medical standards), would seem to relieve it of any charge of being *misbranded* under a *labeling* provision like Sec. 502(j).

However, the Government takes the position and has tried this case on the theory that Sec. 502(j) is designed to protect the public not only from those dangers to health *created by improper labeling*, but also from the potential dangers *inherent* in self-medication, *per se*. These dangers arise primarily from the possibility of a layman, untrained in medical science, making a mistake in *self-diagnosis* and getting into difficulty through taking a *properly labeled* drug under the mistaken impression that he is one of those for whom it is recommended in its labeling.

This being the Government's construction of Sec. 502(j), it devoted its efforts on the trial of this case to the introduction of evidence—over the repeated and continuing objection of your petitioner regarding its materiality (R. 27-8, 51, 178, 183, 439-40, 755, 758, 769, 771)—that laymen, who are untrained in medical science, may have certain *latent* diseases or conditions *of which they are unaware* and incompetent to diagnose; that the use of desiccated thyroid in the presence of such latent diseases or conditions is contra-indicated because it may precipitate an active stage thereof; and that as a result of these potential dangers *inherent* in self-medication with desiccated thyroid, *per se*, laymen should not be permitted to use it *except* upon the prescription and under the continuous supervision of a competent physician.*

Based on evidence of this kind, the trial Court decided that Marmola was "dangerous to health" and *misbranded* within the meaning of Sec. 502(j) because it cannot be

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*This proof consisted of the opinion testimony of a number of expert witnesses (R. 32-125, 126-70, 170-216, 216-314, 384-99, 417-42, 478-553, 556-79, 580-634, 636-40, 640-8, 668-727 & 850-60, 728-54, 777-822 & 860-96, 824-50 & 896-903); testimony concerning the results of a poll taken of various doctors throughout the country by the Food and Drug Administration to determine the so-called consensus of medical opinion regarding the advisability of permitting the public to self-medicate with desiccated thyroid in the Marmola dosage (R. 755-68, 769-76, 1197-1258); and the testimony of half a dozen lay witnesses concerning the unfavorable reactions allegedly suffered by themselves or their relatives from taking desiccated thyroid in the Marmola dosage (R. 314-29 & 352-6, 413-7, 442-55, 469-74, 649-58, 658-67). The *im*materiality of this testimony, even under the Government's theory of the case, is clearly revealed by the fact that the first of these witnesses had taken desiccated thyroid—not for self-medication, but under the supervision of her own physician (R. 319); and by the fact that all of them had taken Marmola *in violation* of one or more of the directions and instructions in the Marmola labeling concerning maximum dosage (R. 663-4), maximum duration of treatment (R. 353, 665), or discontinuing its use in the face of unpleasant symptoms (R. 415, 445, 470-1, 652, 663-5). Hence, none of these persons got into difficulty through taking Marmola *as prescribed* in its labeling (R. 9), the statement of the Circuit Court of Appeals for the Seventh Circuit to the contrary notwithstanding; and, more significant still, their failure to follow such directions could have been readily avoided by them, for it was in no way attributable to a mistake in self-diagnosis.

taken in the recommended dosage in perfect safety in the face of a *mistake in self-diagnosis*, which might result in its use *in violation* of the directions and instructions in the labeling thereof. Stated succinctly, the basis of the trial Court's decision herein *is not* that the use of Marmola *as prescribed* is "dangerous to health" but that its use *otherwise* than as prescribed may be. The pertinent parts of the trial Court's decision so holding (reported in 48 F. *Supp.* 878) read as follows (R. 1313, 1314):

> "Any drug, which for safety in its use requires *diagnosis* and *evaluation*, and when taken in the dosage and with the frequency recommended and suggested in its labeling, may expose the users to disease and pain, is dangerous to health. Marmola is such a drug. In it there is an *inherent* and *potential* danger that may reasonably be expected to attend its use when one considers that it will be used by the strong, the *weak*, the *old*, the *young*, the well, and the *sick*, without *first* having a *physical examination* or a *diagnosis* of their condition by a *competent physician*.
>
> * * * * *
>
> "* * * It places a duty upon the user to make *a self-diagnosis* to determine if he is suffering from hypothyroidism. The layman lacks familiarity with medical terminology. He has little or no knowledge of medical science, and does not possess that skill and learning required to determine whether he is suffering from hypothyroidism. * * *
>
> * * * * *
>
> "The administration of thyroid tablets in Marmola dosages is a dangerous procedure, and should not be undertaken *without a thorough examination of the prospective user by a competent physician, and then only under the supervision of the doctor.*" (Italics ours)

A decree of condemnation having been entered in accordance with the foregoing decision on April 7, 1943, (R.

1327), an appeal was taken therefrom to the Circuit Court of Appeals for the Seventh Circuit on June 22, 1943 (R. 1328), on the following grounds, among others (R. 1329-37):

1. That the *misbranding* provisions of the Federal Food, Drug and Cosmetic Act—like Sec. 502(j)—are purely *labeling* provisions the violation of which is to be determined accordingly; and, hence, it follows that a drug which can be taken as *prescribed* in its *labeling* without danger to health (as defined by recognized medical standards) is not *misbranded* thereunder.

2. That, being purely a *misbranding* provision designed to remove the dangers of self-medication *created by improper labeling*, *Sec.* 502(j) was not designed to prevent self-medication with effective dosages of useful drugs like desiccated thyroid merely because of the potential dangers *inherent* therein, *per se*.

3. That Sec. 502(f) of the statute, by requiring the *labeling* of all drugs to contain warnings of the potential dangers *inherent* in self-medication, *per se*, recognizes the propriety of labeling drugs for self-medication in spite of the presence of such dangers.

4. That Sec. 502(e) of the statute, by making express requirements concerning the labeling of "active," *viz.*, effective dosages of desiccated thyroid for self-medication, recognizes the propriety of labeling it in such doses for such use.*

5. That, although Sec. 503(b) of the statute exempts drugs dispensed on a doctor's prescription from certain of its misbranding provisions, like

*This is so because Sec. 503(b) of the statute exempts drugs dispensed on a doctor's prescription from the requirements of Sec. 502(e), thereby making it applicable to the drugs listed therein *solely* when they are labeled for *self-medication*.

Sec. 502(e), as aforesaid, it does not exempt drugs *so* dispensed from Sec. 502(j); with the result that Sec. 502(j) cannot be construed to prevent the labeling of desiccated thyroid—in effective dosages—for *self-medication*, while permitting its continued labeling for use in such dosages on a doctor's prescription.

6. That, if any doubt remains that Sec. 502(j) is not designed to prevent self-medication with effective dosages of useful drugs, like desiccated thyroid, it is finally set to rest by the *legislative history* of the statute, which clearly discloses that Sec. 502(j) and the other *misbranding* provisions of the statute were not intended to make any useful drug unavailable for self-medication, providing it is *properly labeled*, according to recognized medical standards.

7. That the trial Court's construction of Sec. 502(j) should be avoided because it casts grave doubt on its constitutionality, as being (1) an improper interference by Congress in a matter of purely local concern; (2) an unwarranted attempt to prohibit the right of citizens of this country to medicate themselves, without the existence of any *public* necessity for so doing; and (3) a provision the violation of which entails severe penalties and forfeitures without furnishing any fair or ascertainable standard for gauging compliance therewith in advance of prosecution and punishment.

8. That there is no proof in the record in this case to support a finding that desiccated thyroid in the Marmola dosage is "dangerous to health" (as defined by recognized medical standards), if taken *according to* the directions and instructions in the Marmola labeling—all the proof being to the contrary; and this is the test to be applied in determining whether Marmola is misbranded under

> Sec. 502(j), when it is construed as purely a *labeling* provision the violation of which is to be determined accordingly.

Following the hearing on appeal, the Circuit Court of Appeals for the Seventh Circuit handed down its decision on May 4, 1944 (R. 1353-9), affirming the decision of the trial Court, for *the same fundamental reasons* as those adopted by the trial Court as the basis of its decision herein, as aforesaid. That this is so is apparent upon an analysis of the opinion of the Circuit Court of Appeals (officially reported in 142 F. (2nd) 107), which is epitomized in one of the concluding sentences thereof as follows (R. 1358):

> "It devolved upon the trial court to determine *only* whether it was proved that the drug is dangerous to the public health *at large* if used as recommended [*viz.*, in the dosage recommended] by its vendors."

A moment's reflection will disclose that it is impossible to recommend an effective dosage of any useful drug, known to *materia medica*, that will be *universally* safe under every condition of use and *misuse** attributable to a mistake in *self-diagnosis*; and that self-diagnosis is *a necessary precursor* of all self-medication. Consequently, it follows that, if the test of whether a drug is "dangerous to health" and misbranded under Sec. 502(j) is that laid down in the decision of the trial Court and the Circuit Court of Appeals for the Seventh Circuit affirming the same, then virtually all drugs offered to the public for self-medication are misbranded thereunder, *per se*,

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*That this is true is well recognized by the medical profession (R. 203-4, 440-1, 712), including Dr. Brimmer (R. 1216, 1236), Senior Medical Officer of Federal Food and Drug Administration (R. 1197-8); and has been judicially recognized by this Court in *Coca Cola Co. v. Koke Co.*, 254 U.S. 143, 145; and the Circuit Court of Appeals for the Sixth Circuit in *Raladam Co. v. Fed. Trade Comm.*, 42 F. (2nd) 430, 433-4.

i.e., regardless of the propriety of their labeling; and what has always, heretofore, been regarded as the inalienable right of a citizen of this country to medicate himself with effective dosages of efficacious drugs, that are properly labeled, has become non-existent.

From this it follows that the real question presented by this case is whether *the user* of a proprietary medicine, containing the "generally established" (R. 115) average dosage prescribed by the medical profession of a useful drug—like desiccated thyroid—is prevented by Sec. 502(j) from *himself determining* the desirability or necessity of such use *in his particular case*. If *the user* has such a right under Sec. 502(j)—and it is submitted that he has when it is properly construed—then, *a fortiori*, there can be no violation of Sec. 502(j) in making available to him a preparation with a label showing what it contains and how it should be used—all in accordance with recognized medical standards.

JURISDICTION

(a) The statutory provision which sustains the jurisdiction of this Court to review the decision of the Circuit Court of Appeals for the Seventh Circuit affirming the decision of the trial Court herein is Section 240(a) of the Judicial Code as amended by the Act of February 13, 1925 [43 Stat. 938, c.229; 45 Stat. 54, c.14; 48 Stat. 926, c.426; 28 U.S.C., Sec. 347].

(b) The statute involved in these proceedings is the Federal Food, Drug and Cosmetic Act of 1938 [52 Stat. 1040, c.675; 21 U.S.C., Secs. 301 et seq.], and particularly Sec. 502(j) thereof [21 U.S.C., Sec. 352(j)] which reads as follows:

> "Sec. 502. A drug or device shall be deemed to be misbranded—
>
> "(j) If it is dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof."

(c) The decision of the Circuit Court of Appeals for the Seventh Circuit, of which review is sought, was filed and judgment entered thereon on May 4, 1944 (R. 1353-9). This case falls within the jurisdictional provision relied on for the reasons stated, *infra*, pp. 14-18, under the heading "Reasons Relied On For Allowance Of The Writ."

QUESTIONS PRESENTED

I. In view of the applicable decision of this Court in *McDermott v. Wisconsin*, 228 U.S. 115, 133, is Sec. 502(j) purely a *labeling* provision the violation of which is to be determined accordingly—thereby making "the *label* is the *means* of *vindication* and the *basis* of *punishment*" in deciding whether a drug is misbranded thereunder; *or* is the test of *misbranding* under Sec. 502(j) whether there are any potential dangers *inherent* in *self-medication* with *effective* dosages of a drug?

II. In view of the wording of the other misbranding provisions of the statute in *pari materia* with Sec. 502(j), and its legislative history, is Sec. 502(j) subject to a construction which will prevent the labeling of *effective* dosages of useful drugs—like desiccated thyroid—for *self-medication*, because of the potential dangers *inherent* therein, and, at the same time, permit their continued labeling for use on a doctor's prescription?

III. Does the construction placed on Sec. 502(j) by the decision of the Circuit Court of Appeals for the Seventh Circuit, affirming the decision of the trial Court herein, cast grave doubt upon its constitutionality?

IV. Does the record herein contain evidence which—as a matter of law—will support a finding that Marmola is *misbranded* under Sec. 502(j), when it is construed as purely a *labeling* provision the violation of which is to be determined accordingly?

REASONS RELIED ON FOR ALLOWANCE OF THE WRIT

1. The decision of the Circuit Court of Appeals for the Seventh Circuit *herein* is in conflict with an applicable decision of this Court in *McDermott v. Wisconsin*, 228 U.S. 115, defining the *purpose* and *scope* of "misbranding" provisions—such as Sec. 502(j) of the Federal Food, Drug and Cosmetic Act. The pertinent parts of this Court's opinion, in this connection, are found on pages 130, 131 and 132-3 thereof and read as follows:

> "* * * Within the limitations of its right to regulate interstate commerce, Congress manifestly is aiming at the contents of the package as it shall reach the consumer, for whose protection the act was primarily passed, and *it is the branding* upon the package which contains the article intended for consumption itself *which is the subject-matter of regulation.* * * *
>
> "The *object* of the statute is to prevent *the misuse of the facilities of interstate commerce* in *conveying to* and *placing before* the consumer *misbranded* and adulterated articles of medicine or food, and in order that its protection may be afforded to those who are intended to receive its benefits the brands regulated must be upon the packages intended to reach the purchaser. This is *the only practical or sensible construction of the act*, and, for the reasons we have stated, we think the requirements of the act *as so construed* clearly *within the powers of Congress* over the facilities of interstate commerce, and such has been the construction generally placed upon the act by the Federal courts. (Citing cases)
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> * * * * * *
>
> "The *label* upon the unsold article *is* in the one case *the evidence* of the shipper that he has complied

> with the act of Congress, while in the other, by its misleading and false character, it furnishes the proof upon which the Federal authorities depend to reach and punish the shipper and to condemn the goods. If truly labeled within the meaning of the act his goods are immune from seizure by Federal authority; if the label is false or misleading within the terms of the law the goods may be seized and condemned. In other words *the label* is the *means of vindication* or the *basis of punishment* in determining the character of the interstate shipment dealt with by Congress. * * *" (Italics ours)

As hereinabove pointed out (*supra*, pp. 6-10), the Circuit Court of Appeals for the Seventh Circuit, in affirming the decision of the trial Court herein, did not apply a *labeling* test in determining that Marmola is misbranded under Sec. 502(j) of the Federal Food, Drug and Cosmetic Act. Instead, the test applied was whether Marmola is *inherently* dangerous for self-medication, *per se*, regardless of the propriety of its labeling. Inasmuch, as such a test does not make the Marmola *labeling* "the means of vindication or the basis of punishment" in determining whether Marmola is misbranded under Sec. 502(j), the decision and judgment of the Circuit Court of Appeals for the Seventh Circuit herein is clearly in conflict with the applicable decision of this Court in *McDermott v. Wisconsin, supra.* As a result it is submitted that this petition for a writ of certiorari to review the same should be granted for this reason alone (Rule 38, Sec. 5(b) of the Rules of this Court; *San Giorgio I v. Rheinstrom Co.*, 294 U.S. 494, 495-6; *National Labor Relations Board v. Newport News Co.*, 308 U.S. 241, 244; *Ford Motor Co. v. Beauchamp*, 308 U.S. 331, 332; *Yearsley v. Ross Construction Co.*, 309 U.S. 18, 20; *Helvering v. Fitch*, 309 U.S. 149, 150; *Russell v. Todd*, 309 U.S. 280, 284; *Helvering v. Leonard*, 310 U.S. 80, 91; *West India Oil Co. v. Domenech*, 311 U.S. 20, 24; *Department of Treasury of Indiana v. Wood Preserving Corp.*, 313 U.S. 62, 63; *D'Oench, Duhme & Co. v. Federal Deposit Insurance Corp.*, 315 U.S. 447, 455).

2. This case presents an important question of federal law which has not been, but should be, settled by this Court. As has been pointed out (*supra*, pp. 10-11), the potential dangers *inherent* in the use of *effective* dosages of desiccated thyroid for self-medication are *inherent* in self-medication with all useful drugs to a varying degree. Inasmuch as the construction placed on Sec. 502(j), by the Circuit Court of Appeals for the Seventh Circuit herein, makes the presence or absence of such dangers the criterion of whether a drug is misbranded thereunder, it follows that virtually all drugs are misbranded thereunder, *per se*, if they are labeled in effective dosage for use by the public for self-medication.

This being so, the important question of federal law which has not been, but should be, settled by this Court is: Can Sec. 502(j) be construed in such a manner as to make virtually all useful drugs known to *materia medica*, including desiccated thyroid, unavailable to the public in *effective* dosages for self-medication, *viz.*, except on a doctor's prescription, (1) in view of its wording, the wording of other misbranding provisions of the statute in *pari materia* therewith, and its legislative history, and (2) without casting grave doubt upon its constitutionality?

The final determination by this Court of this question of the proper construction and application of a new federal statute, promulgated for the public welfare, is clearly of great importance not only to your petitioner, but to those engaged in administering and enforcing the statute; and, in a most vital sense, to the public at large. Hence, it is submitted that this furnishes an additional reason which should impel this Court to grant this petition (Rule 38, Sec. 5(b) of the Rules of this Court; *Worcester County Trust Co. v. Riley*, 302 U.S. 292, 296; *West India Oil Co. v. Domenech*, 311 U.S. 20, 24; *Miles v. Illinois Central R. Co.*, 315 U.S. 698, 700-1; *O'Donnell v. Great Lakes Dredge & Dock Co.*, 318 U.S. 36, 38; *Federal Security Administrator v. Quaker Oats Co.*, 318 U.S. 218, 223; *Maricopa County v. Valley National Bank*, 318 U.S. 357,

360; *Helvering v. Griffiths*, 318 U.S. 371, 372; *Ecker v. Western Pacific R. Co.*, 318 U.S. 448, 452; *Emil v. Hanley*, 318 U.S. 515, 517).

3. Finally, when Sec. 502(j) is construed as purely a labeling provision the violation of which is to be determined accordingly, the record is devoid of proof to support a finding that Marmola is misbranded thereunder. As has been pointed out (*supra*, pp. 3-5), the proof is all the other way—even taking into consideration the testimony of the Government's witnesses alone. In other words, the Marmola *labeling*, in recommending an average daily dosage of 2 grains of desiccated thyroid for people with obesity caused by hypothyroidism who are otherwise normal and healthy (R. 8), is in accordance with recognized medical practice. The same thing is true of the directions in the Marmola labeling to stop taking it if any unpleasant effects are experienced until they disappear, and then resume in one-half the former dosage (R. 9).

While this Court will not review the concurrent findings of fact of a trial court and a circuit court of appeals where there is evidence in the record to support the same, it has indicated the propriety of its doing so on more than one occasion where, as in the instant case, there is no evidence in the record to support such concurrent findings and where the lower courts have failed to apply correct legal principles to the undisputed evidence (*Sanitary Refrigerator Co. v. Winters*, 280 U.S. 30, 36; *General Talking Pictures Corp. v. Western Electric Corp.*, 304 U.S. 175, 178; *United States v. Appalachian Power Co.*, 311 U.S. 377, 403-4; *Seago, Administratrix v. New York Central R. Co.*, 315 U.S. 781; *Williams Mfg. Co. v. United Shoe Machinery Co.*, 316 U.S. 364, 365). Therefore, it is submitted that the foregoing is another sound reason for granting this petition.

Wherefore your petitioner prays that a Writ of Certiorari issue under the seal of this Court to the end that

this cause may be reviewed and determined by this Court, as provided for by the statutes of the United States in such case made and provided; that the judgment entered in the Circuit Court of Appeals for the Seventh Circuit be reversed by this Court, and for such further relief as to this Court may seem proper.

RALADAM COMPANY, *Petitioner,*

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